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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,355	06/23/98	KUSHNER	P 23070-080510

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EXAMINER

PAK, M

ART UNIT	PAPER NUMBER
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1646

15

DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/103,355

Applicant(s)

Kushner et al.

Examiner

Michael Pak

Group Art Unit

1646

☒ Responsive to communication(s) filed on Oct 16, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

*Response to Amendment*

1. Amendments filed 16 October 2000 (Paper No. 14) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 16 October 2000 (Paper No. 14), have been fully considered but they are not found persuasive.

*Double Patenting*

4. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,723,291. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Applicants argue that the conflicting patent '291 claims do not teach the nuclear transcription ligand. However, the method claims of '291 is encompassed by the present claims because the AP-1 proteins of '291 is the nuclear transcription ligand and receptor. Furthermore, claim 3 further limits the methods to have endogenous estrogen receptor and exogenous estrogen

receptors which would provide both the estrogen receptor and the cognate receptor. The claims of '291 patent must be examined as to the scope of the claims as interpreted by the specification.

*Claim Rejections - 35 USC § 102*

5. Claims 1-5, 8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Kushner et al. ((AB); U.S. 5,723,291).

The teachings of Kushner et al. has been set forth in the previous office action.

The newly amended claim limitations "cognate" does not exclude the teachings of Kushner et al. because of the specification disclosure on page 6 of cognate receptor. The newly amended claim limitations for the negative control is taught by transfection with or without jun or fos at the same time or singly (columns 10 and 13). Furthermore, Kushner et al. teach a method using MDA453 cells (columns 5, 14 and 15) which express endogenous estrogen receptor by transfecting with estrogen receptor fusion protein (columns 13-15). The estrogen receptor fusion protein is not excluded by the term "cognate receptor" and the ligands are estrogens or antiestrogens. The essays are performed with and without hormones (columns 13-15).

Applicants argue that limitation b) is not taught by Kushner et al. However, both fos and jun are in the methods of the

assays in order for the AP-1 sites to work and thus are in contact with the cells.

6. Claims 1-5, 8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by GAUB et al.((AV); Cell, 1990).

GAUB et al. teaching has been set forth in the previous office action.

Applicants argue that cognate receptor is defined in the specification on page 6 and excludes fos and jun. However, the term "transcription factor ligand" as defined is a generic term and does not exclude fos and jun because fos and jun are transcription factors which bind and thus are receptors as well. Since steroid receptors are transcription factors they would be encompassed as well by the generic term "cognate receptor" as well as fos and jun.

7. Claims 1-5, 8 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al.((B); U.S. 5,639,592).

Evans et al. teaching has been set forth in the last office action.

Applicants argue that the reference does not teach the method in which the cell is contacted with both jun or fos and with an agent that activates transcription of gene under the control of an AP-1 site. However, the column 7 teaches the

method using AP-1 proteins by exogenous expression. Furthermore, column 5 teaches the method using AP-1 proteins endogenously or by administering fos or jun. Column 6 teaches the method using the estrogen receptor. The pages 7-8 of the specification's definition of "AP-1 mediated estrogen activity" is generic to the teachings of Evans et al. and does not exclude the teachings of Evans et al.

8. Claims 1-2, 4, 8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfahl et al. ((A); U.S. 6,004,748).

Pfahl et al. teaching was set forth in the last office action.

Applicants argue that the reference does not teach the method in which the cell is contacted with both jun or fos and with an agent that activates transcription of gene under the control of an AP-1 site. However, the columns 2 and 4 teaches the method using AP-1 proteins, cJun and cFos, by exogenous expression. Furthermore, column 2 teaches the method using AP-1 proteins endogenously expressing fos or jun. Column 2 teaches the method using the estrogen receptor. The pages 7-8 of the specification's definition of "AP-1 mediated estrogen activity" is generic to the teachings of Pfahl et al. and does not exclude the teachings of Pfahl et al.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are cumulative references with Kushner et al.((AB); U.S. 5,723,291), Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990).

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.  
Faxed draft or informal communications with the examiner should be directed to  
(703) 308-0294.

Any inquiry of a general nature or relating to the status of this  
application or proceeding should be directed to the Group receptionist whose  
telephone number is (703) 308-0196.

*Michael D. Pak*

Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
29 December 2000